

APR 22 2002



CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley
Regulatory Specialist

Proprietary Name: Distal Radius Plating System

Common or Usual Name: plate system

Classification Name: Plate, fixation, bone (888.3030);
[REDACTED]

Device Product Code: HRS [REDACTED]

Substantially Equivalent Device(s): Bionx Biodegradable Threaded Distal Radius Screw (K974876) , Resorbable Bone Pins (K011522)

Device Description: The Distal Radius Plating System consists of resorbable dorsal and volar plates. The plates are used in conjunction with 2.5mm resorbable screws. The plates and screws are made of a L-lactide/glycolide co-polymer.

Intended Use: The Distal Radius Plating System is indicated for use in open reduction and internal fixation of Frykman I-IV dorsally displaced Colles fractures, osteotomies, and carpal fusions of the distal radius in the presence of appropriate immobilization.

Summary of Technologies: Extensive testing determined that the Distal Radius Plating System and Bionx Biodegradable Threaded Distal Radius Screw have equivalent mechanical properties. Biocompatibility testing was completed and demonstrated that the co-polymer material is non-toxic, non-mutagenic, and non-pyrogenic,

Non-clinical Testing: In-vitro mechanical testing was completed and demonstrated that the Distal Radius Plating System was equivalent to the predicate devices.

Clinical Testing: No clinical data was completed.

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APR 22 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Verstynen
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K020819

Trade/Device Name: Distal Radius Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 31, 2002
Received: March 13, 2002

Dear Ms. Verstynen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

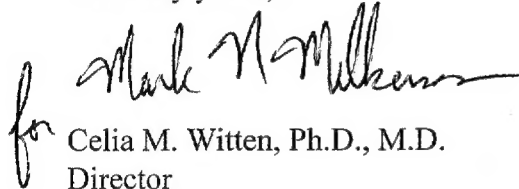
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (IF KNOWN): K020819

Device Name: Distal Radius Plating System

Indications for Use:

The Distal Radius Plating System is indicated for use in open reduction and internal fixation of Frykman type I-IV dorsally displaced Colles fractures, osteotomies, and carpal fusions of the distal radius in the presence of appropriate immobilization.

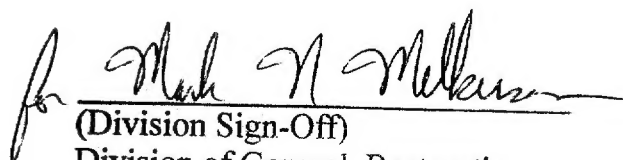
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐
 (Optional Format 1-2-96)


 (Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K020819